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Date	2.8.79
Certifier	C. W. M. DAY

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N-0124]

**Agency Information Collection Activities: Proposed Collection; Comment Request; Premarket Notification for a New Dietary Ingredient**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the procedure by which a manufacturer or distributor of dietary supplements or of a new dietary ingredient is to submit information to FDA on which it has concluded that a dietary supplement containing a new dietary ingredient will reasonably be expected to be safe.

**DATES:** Submit written comments on the collection of information by (*insert date 60 days after date of publication in the **Federal Register***).

**ADDRESSES:** Submit written comments on the collection of information to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

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**FOR FURTHER INFORMATION CONTACT:** Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth below.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**New Dietary Ingredient Premarket Notification—21 CFR 190.6 (OMB Control Number 0910-0330—Extension)**

*Description:* Section 413(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 350b(a)) provides for the notification of the Secretary of Health and Human Services (the Secretary)

(and by delegation FDA) at least 75 days before the introduction or delivery for introduction into interstate commerce of a dietary supplement that contains a new dietary ingredient.

The agency established 21 CFR 190.6 as the procedural regulation for this program. This regulation provides details of the administrative procedures associated with the submission and identifies the information that must be included in the submission in order to meet the requirements of section 413(a) of the act and to show the basis on which a manufacturer or distributor of a new dietary ingredient or a dietary supplement containing a new dietary ingredient has concluded that the dietary supplement containing such dietary ingredient will reasonably be expected to be safe.

*Description of Respondents:* Businesses or other for-profit organizations.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

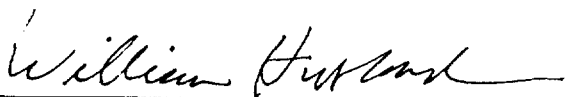
21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
190.6	11	1	11	20	220

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

The agency believes that there will be minimal burden on the industry to generate data to meet the requirements of the premarket notification program because the agency is requesting only that information that the manufacturer or distributor should already have developed to satisfy itself that a dietary supplement containing a new dietary ingredient is in full compliance with the act. However, the agency estimates that extracting and summarizing the relevant information from the company's files, and presenting it in a format that will meet the requirements of section

413 of the act, will require a burden of approximately 20 hours of work per submission. This estimate is based on the average number of premarket notifications received by the agency in the last 3 years.

Dated: February 1, 1999



William K. Hubbard  
Associate Commissioner for Policy Coordination

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